Notice of Allowability	Application No.	Applicant(s)	
	10/723,681	ROTH ET AL.	
	Examiner	Art Unit	
	Jehanne S. Sitton	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *7/18/2008*.

2. ☒ The allowed claim(s) is/are *92-164*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 12/2007
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Bruce Grant on 10/22/2008.

The application has been amended as follows:

In claim 92, line 17, delete the recitation of "a" between the words 'and' and 'complement' and insert instead the term --the--.

In claim 92, line 33, delete the recitation of "a" between the words 'and' and 'complement' and insert instead the term –the--.

In claim 94, line 8, insert the term --of—between the terms 'presence' and 'a'.

In claim 128, line 17, delete the recitation of "a" between the words 'and' and 'complement' and insert instead the term --the--.

In claim 128, line 33, delete the recitation of "a" between the words 'and' and 'complement' and insert instead the term –the--.

In claim 128, starting at line 37, delete the recitation of "not administering a breast cancer detection procedure to a human subject determined to have a decreased risk of breast cancer based on the presence of one or more polymorphic variants of (b)" and insert instead – determining that a human subject is at decreased risk of breast cancer based on the presence of one or polymorphic variants of (b) and not administering a breast cancer detection procedure--.

In claims 95-126, and 132-163, line 2, delete the recitation of "a" between the words 'and' and 'complement' and insert instead the term --the--.

In claim 130, line 8, insert the term --of—between the terms 'presence' and 'a'.

2. The following is an examiner's statement of reasons for allowance: the claims are directed to: A method for determining whether a human subject is at an increased risk or decreased risk of breast cancer, which comprises: (a) detecting in a nucleic acid of the human subject the presence of a polymorphic variant selected from the group consisting of a guanine corresponding to position 7573 of SEQ ID NO: 2, a guanine corresponding to position 13903 of SEQ ID NO: 2, an adenine corresponding to position 23826 of SEQ ID NO: 2, an adenine corresponding to position 26057 of SEQ ID NO: 2, a thymine corresponding to position 26361 of SEQ ID NO: 2, an adenine corresponding to position 26599 of SEQ ID NO: 2, an adenine corresponding to position 26812 of SEQ ID NO: 2, a cytosine corresponding to position 27069 of SEQ ID NO: 2, an adenine corresponding to position 35127 of SEQ ID NO: 2, a thymine corresponding to position 35222 of SEQ ID NO: 2, a cytosine corresponding to position 36424 of SEQ ID NO: 2, a cytosine corresponding to position 46176 of SEQ ID NO: 2, a cytosine corresponding to position 50452 of SEQ ID NO: 2, a guanine corresponding to position 61093 of SEQ ID NO: 2, an adenine corresponding to position 62572 of SEQ ID NO: 2, a guanine corresponding to position 70759 of SEQ ID NO: 2, and the complement of the foregoing; or (b) detecting in a nucleic acid of the human subject the presence of a polymorphic variant selected from the group consisting of an adenine corresponding to position 7573 of SEQ ID NO: 2, a cytosine corresponding to position 13903 of SEQ ID NO: 2, a thymine corresponding to position 23826 of SEQ ID NO: 2, a guanine corresponding to position 26057 of SEQ ID NO: 2, a

3. cytosine corresponding to position 26361 of SEQ ID NO: 2, a guanine corresponding to position 26599 of SEQ ID NO: 2, a guanine corresponding to position 26812 of SEQ ID NO: 2, a thymine corresponding to position 27069 of SEQ ID NO: 2, a guanine corresponding to position 35127 of SEQ ID NO: 2, a guanine corresponding to position 35222 of SEQ ID NO: 2, a thymine corresponding to position 36424 of SEQ ID NO: 2, a guanine corresponding to position 46176 of SEQ ID NO: 2, a thymine corresponding to position 50452 of SEQ ID NO: 2, a cytosine corresponding to position 61093 of SEQ ID NO: 2, a guanine corresponding to position 62572 of SEQ ID NO: 2, an adenine corresponding to position 70759 of SEQ ID NO: 2, and the complement of the foregoing; whereby it is determined that the subject is at an increased risk of breast cancer based on the presence of one or more of the polymorphic variants of (a), and whereby it is determined that the subject is at a decreased risk of breast cancer based on the presence of one or more of the polymorphic variations of (b). The claims are also drawn to methods for determining whether a breast cancer detection procedure is administered to a human subject which comprises (a) detecting in a nucleic acid of the human subject the presence of a polymorphic variant selected from the group consisting of a guanine corresponding to position 7573 of SEQ ID NO: 2, a guanine corresponding to position 13903 of SEQ ID NO: 2, an adenine corresponding to position 23826 of SEQ ID NO: 2, an adenine corresponding to position 26057 of SEQ ID NO: 2, a thymine corresponding to position 26361 of SEQ ID NO: 2, an adenine corresponding to position 26599 of SEQ ID NO: 2, an adenine corresponding to position 26812 of SEQ ID NO: 2, a cytosine corresponding to position 27069 of SEQ ID NO: 2, an adenine corresponding to position 35127 of SEQ ID NO: 2, a thymine corresponding to position 35222 of SEQ ID NO: 2, a cytosine corresponding to position 36424

of SEQ ID NO: 2, a cytosine corresponding to position 46176 of SEQ ID NO: 2, a cytosine corresponding to position 50452 of SEQ ID NO: 2, a guanine corresponding to position 61093 of SEQ ID NO: 2, an adenine corresponding to position 62572 of SEQ ID NO: 2, a guanine corresponding to position 70759 of SEQ ID NO: 2, and the complement of the foregoing; or (b) detecting in a nucleic acid of the human subject the presence of a polymorphic variant selected from the group consisting of an adenine corresponding to position 7573 of SEQ ID NO: 2, a cytosine corresponding to position 13903 of SEQ ID NO: 2, a thymine corresponding to position 23826 of SEQ ID NO: 2, a guanine corresponding to position 26057 of SEQ ID NO: 2, a cytosine corresponding to position 26361 of SEQ ID NO: 2, a guanine corresponding to position 26599 of SEQ ID NO: 2, a guanine corresponding to position 26812 of SEQ ID NO: 2, a thymine corresponding to position 27069 of SEQ ID NO: 2, a guanine corresponding to position 35127 of SEQ ID NO: 2, a guanine corresponding to position 35222 of SEQ ID NO: 2, a thymine corresponding to position 36424 of SEQ ID NO: 2, a guanine corresponding to position 46176 of SEQ ID NO: 2, a thymine corresponding to position 50452 of SEQ ID NO: 2, a cytosine corresponding to position 61093 of SEQ ID NO: 2, a guanine corresponding to position 62572 of SEQ ID NO: 2, an adenine corresponding to position 70759 of SEQ ID NO: 2, and the complement of the foregoing; and administering a breast cancer detection procedure to a human subject determined to have an increased risk of breast cancer based on the presence of the one or more polymorphic variants of (a), or determining that a human subject is at decreased risk of breast cancer based on the presence of one or polymorphic variants of (b) and not administering a breast cancer detection procedure.

The claims are allowable over the prior art because the prior art does not teach or fairly suggest an association between the claimed polymorphic variant alleles and increased or decreased risk of breast cancer.

4. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0752. The examiner can normally be reached Monday, Wednesday and Thursday from 9:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

/Jehanne Sitton/
Primary Examiner
Art Unit 1634